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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/158,272	DIAS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph T. Voitach	1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after final amendment filed November 17, 2003.
2. ☒ The allowed claim(s) is/are 27, 28, 33, 35-44, 46, 47, 50, 53, 55-57, 62-66, 68-83.
3. ☒ The drawings filed on 22 September 1998 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.            |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                  |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|   | 9 <input type="checkbox"/> Other _____.   |

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### **DETAILED ACTION**

This application filed September 22, 1998, claims benefit of provisional application 60/062,994, filed October 23, 1997, and claims priority to foreign application 9703663-6 filed October 8, 1997 in Sweden.

Applicants' after final amendment filed November 17, 2003 has been received and entered. Claims 60, 61 and 67 have been canceled. Claims 27, 28, 39, 40, 43, 53, 55, 64, 65 and 66 have been amended. Claims 68-83 have been added. Claims 27, 28, 33, 35-44, 46, 47, 50, 53, 55-57, 62-66 and 68-83 are pending and currently under examination.

### ***Examiner's Comment***

It is noted that in the after final amendment claim 45 was indicated to be pending, however claim 45 was canceled in the amendment filed April 10, 2003. Applicants were contacted and it was indicated that presentation of claim 45 was in error. Because claim 45 was previously canceled, Examiner indicated that no further action would be necessary and that the error would simply be noted in the notice of allowance

### ***Reasons for allowance***

The following is an examiner's statement of reasons for allowance:

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As indicated in the final office action, claims 28, 43, 44, 46, 47, 55, 56, 57, 64, 65 were allowed. All claims are free of the art of record because the art fails to teach or make obvious the use of beta recombinase in transgenic animal methodology. At the time of filing a prokaryotic Beta recombinase was isolated from a Gram-positive broad host range plasmid PSM19035, originally isolated from *S. pyogenes* and shown to require additionally host cofactors, such as Hbsu from *S. subtilis*, to affect recombination between two *six* site target sequences. Though at the time of filing beta recombinase was known in the art as a member of the resolvase/invertase family of recombinases, and other recombinases (Cre and Flp) were used in the art in the generation of transgenic animals, these recombinases are classified in the Int family of recombinases. Importantly, the Int family of recombinases do not require additional cofactors. The present specification is the first to demonstrate that other host non-prokaryotic factors, such as the mammalian cofactor HMG, are able to serve as host factors in the presence of beta recombinase and polynucleotide sequences between two *six* sites in generating an intramolecular recombination event in mammalian cells.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

*Deborah Crouch*  
DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1801/630